



PATENT Attorney Docket No.: JHU1800-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Se-Jin Lee et al.

Art Unit: 1645

Application No.:

10/665,374

Examiner: Not yet assigned

Filed:

September 16, 2003

Title: META

METALLOPROTEASE ACTIVATION OF MYOSTATIN, AND

METHODS OF MODULATING MYOSTATIN ACTIVITY

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL SHEET

Sir:

Transmitted herewith for the above-identified application please find:

- 1. Information Disclosure Statement (2 pages);
- 2. PTO-1449 Forms (3 pages);
- 3. Thirty-five (35) References
- 4. Return Postcard.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, **November 18, 2005**, in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Cara Grifone

(Name of Person Mailing Paper)

November 18, 200

(Date

In re Application of:

Se-Jin Lee et al.

Application No.: 10/665,374 Filing Date: September 16, 2003

Page 2

No fee is believed due in connection with this Information Disclosure Statement. This Information Disclosure Statement is being filed prior to receipt of a first Office Action. Applicants do not believe any others fees are due; however, if any other fee is required, authorization is hereby given to charge Deposit Account No. 07-1896.

Respectfully submitted,

Attorney Docket No. JHU1800-3

Date: November 18, 2005

Lisa A. Haile, J.D., Ph.D. Registration No.: 38,347 Telephone: (858) 677-1456 Facsimile: (858) 677-1465

USPTO CUSTOMER NUMBER 28213 DLA PIPER RUDNICK GRAY CARY US LLP 4365 Executive Drive, Suite 1100 San Diego, CA 92121-2133



PATENT

Attorney Docket No.: JHU1800-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Se-Jin Lee et al.

Art Unit: 1645

Application No.:

10/665,374

Examiner: Not yet assigned

Filed:

September 16, 2003

Title:

METALLOPROTEASE ACTIVATION OF MYOSTATIN, AND

METHODS OF MODULATING MYOSTATIN ACTIVITY

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §1.97, enclosed is Form PTO-1449 which lists the references relating to the above-identified application. A copy of each reference is also enclosed for your convenience.

It is respectfully requested that these references be considered in the examination of this application and their consideration be made of written record in the application file.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, November 18, 2005 in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

of Person Mailing

November 18, 2005

In re Application of:

Se-Jin Lee

Application No.: 10/665,374 Filing Date: September 16, 2003

Page 2

No fee is believed due in connection with this Information Disclosure Statement. This Information Disclosure Statement is being filed prior to receipt of a first Office Action. Applicants do not believe any others fees are due; however, if any other fee is required, authorization is hereby given to charge Deposit Account No. 07-1896.

Respectfully submitted,

Attorney Docket No. JHU1800-3

Date: November 18, 2005

Lisa A. Haile, J.D., Ph.D.

Reg. No.: 38,347

Telephone: (858) 677-1456 Facsimile: (858) 677-1465

USPTO CUSTOMER NUMBER 28213 DLA PIPER RUDNICK GRAY CARY US LLP 4365 Executive Drive, Suite 1100

San Diego, CA 92121-2133



INFORMATION DISCLOSURE CITATION

F/		
Atty. Docker No.	JHU1800-3	Appln. No. 10/665,374
Applicant	Se-Jin Lee et al.	·
Filing Date	September 16, 2003	Group: 1645

U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	Publication No. 2003-0104406 (U.S. Appln. No. 10/071,499)	Published June 5, 2003	Wolfman et al.	435	6	February 8, 2002
	5,994,618	11/30/1999	Lee et al.	800	18	February 5, 1997

FOREIGN PATENT DOCUMENTS							
		Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
				,			

•	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	Blader et al., "Cleavage of the BMP-4 Antagonist Chordin by Zebrafish Tolloid", Science 278:1937-1940 (1997)
	Bogdanovich et al., "Functional Improvement of Dystrophic Muscle by Myostatin Blockade", <i>Nature</i> 420:418-421 (2002)
	D'Angelo et al., "Authentic Matrix Vesicles Contain Active Metalloproteases (MMP)", J. Biol. Chem. 276:11347-11353 (2001)
	Donoghue et al., "Rostrocaudal Gradient of Transgene Expression in Adult Skeletal Muscle", PNAS 88:5847-5851 (1991)
	Gonzalez-Cadavid et al., "Organization of the Human Myostatin Gene and Expression in Healthy Men and HIV-Infected Men With Muscle Wasting", PNAS 95:14938-14943 (1998)
	Hill et al., "The Myostatin Propeptide and the Follistatin-Related Gene are Inhibitory Binding Proteins of Myostatin in Normal Serum", <i>J. Biol. Chem.</i> 277:40735-40741 (2002)
	Hill et al., "Regulation of Myostatin in Vivo by Growth and Differentiation Factor-Associated Serum Protein-1: A Novel Protein with Protease Inhibitor and Follistatin Domains", Mol. Endocrin. 17:1144-1154 (2003)
	Kessler et al., "Bone Morphogenetic Protein-1: The Type I Procollagen C-Proteinase", Science 271:360-362 (1996)
	Lee et al., "Regulation of Myostatin Activity and Muscle Growth", PNAS, 98:9306-9311 (2001)
	Lee et al., "Analysis of Site-Directed Mutations in Human Pro-a2(I) Collagen Which Block Cleavage by the C-Proteinase", J. Biol. Chem. 265:21992-21996 (1990)

INFORMATION DISCLOSURE CITATION

Atty. Docket No.	JHU1800-3	Appln. No.	10/665,374
Applicant	Se-Jin Lee et al.		
Filing Date	September 16, 2003	Group:	1645

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
Li et al., "The C-Proteinase that Processes Procollagens to Fibrillar Collagens is Identical to the Protein Previously Identified as Bone Morphogenic Protein-1", PNAS 93:5127-5130 (1996)
Lyons et al., "Proteolytic Activation of Latent Transforming Growth Factor-β from Fibroblast-Conditioned Medium", <i>J. Cell Biol.</i> 106:1659-1665 (1988)
Maeda et al., "Activation of Latent Transforming Growth Factor β1 by Stromelysin 1 in Extracts of Growth Plate Chondrocyte-Derived Matrix Vesicles", <i>J. Bone Min. Res.</i> 16:1281-1290 (2001)
Marques et al., "Production of a DPP Activity Gradient in the Early Drosophilia Embryo through the Opposing Actions of the SOG and TLD Proteins", Cell 91:417-426 (1997)
McPherron et al., "Double Muscling in Cattle Due to Mutations in the Myostatin Gene", PNAS 94:12457-12461 (1997)
McPherron et al., "Regulation of Skeletal Muscle Mass in Mice by a New TGF-β Superfamily Member", <i>Nature</i> 387:83-90 (1997)
McPherron et al., "Suppression of Body Fat Accumulation in Myostatin-Deficient Mice", J. Clin. Invest. 109:595-601 (2002)
Pappano et al., "Use of BMP1/TII1 Doubly Homozygous Null Mice and Proteomics to Identify and Validate In Vivo Substrates of Bone Morphogenetic Protein 1/Tolloid-Like Metalloproteinases", Mol. Cell Biol. 23:4428-4438 (2003)
Piccolo et al., "Cleavage of Chordin by Xolloid Metalloprotease Suggests a Role for Proteolytic Processing in the Regulation of Spemann Organizer Activity", Cell 91:407-416 (1997)
Sato et al., "Inhibition of Endothelial Cell Movement by Pericytes and Smooth Muscle Cells: Activation of a Latent Transforming Growth Factor-\$1-Like Molecule by Plasmin During Co-Culture", J. Cell Biol. 109:309-315 (1989)
Scott et al., "Mammalian BMP-1/Tolloid-Related Metalloproteinases, Including Novel Family Member Mammalian Tolloid-Like 2, Have Differential Enzymatic Activities and Distributions of Expression Relevant to Patterning and Skeletogenesis", <i>Devel. Biol.</i> 213:283-300 (1999)
Scott et al., "Bone Morphogenetic Protein-1 Processes Probiglycan", J. Biol. Chem. 275:30504-30511 (2000)
Sternberg et al., "Identification of Upstream and Intragenic Regulatory Elements that Confer Cell- Type-Restricted and Differentiation-Specific Expression on the Muscle Creatine Kinase Gene", Mol. Cell Biol. 8:2896-2909 (1988)
Takahara et al., "Bone Morphogenetic Protein-1 and a Mammalian Tolloid Homologue (mTld) Are Encoded by Alternatively Spliced Transcripts Which Are Differentially Expressed in Some Tissues", J. Biol. Chem. 269:32572-32578 (1994)
Takahara et al., "Characterization of a Novel Gene Product (Mammalian Tolloid-like) with High Sequence Similarity to Mammalian Tolloid/Bone Morphogenetic Protein-1", <i>Genomics</i> 34:157-165 (1996)
Thies et al., "GDF-8 Propeptide Binds to GDF-8 and Antagonizes Biological Activity by Inhibiting GDF-8 Receptor Binding", <i>Growth Factors</i> 18:251-259 (2001)

INFORMATION DISCLOSURE CITATION

Atty. Docket No	o. JHU1800-3	Appln. No. 10/665,374	
Applicant	Se-Jin Lee et al.		·
Filing Date	September 16, 2003	Group: 1645	,

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
Uzel et al., "Multiple Bone Morphogenetic Protein 1-Related Mammalian Metalloproteinases Process Pro-Lysyl Oxidase at the Correct Physiological Site and Control Lysyl Oxidase Activation in Mouse Embryo Fibroblast Cultures", J. Biol. Chem. 276:22537-22543 (2001)				
Yu et al., "Cell Surface-Localized Matrix Metalloproteinase-9 Proteolytically Activates TGF-β and Promotes Tumor Invasion and Angiogenesis", Genes Dev. 14:163-176 (2000)				
Wagner et al., "Loss of Mysostatin Attenuates Severity of Muscular Dystrophy in mdx Mice", Ann. Neurol. 52:832-836 (2002)				
Whittemore et al., "Inhibition of Myostatin in Adult Mice Increases Skeletal Muscle Mass and Strength", Biochem. Biophys. Res. Comm. 300:965-971 (2003)				
Wozney et al., "Novel Regulators of Bone Formation: Molecular Clones and Activities", Science 242:1528-1534 (1988)				
Zimmers et al., "Induction of Cachexia in Mice by Systemically Adminstered Myostatin", <i>Science</i> 296:1486-1488 (2002)				

Examiner Date Considered		Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP through citation if not in conformance and not considered. Include copy of this form communication to applicant.		f not in conformance and not considered. Include copy of this form with next
Form PTO 14	149	Patent and Trademark Office - U.S. Department of Commerce